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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,115	06/23/2005	Ola Karlsson	1103326-0781	8848

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
WU, IVES J	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,115	KARLSSON ET AL.	
	Examiner	Art Unit	
	Ives Wu	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/13/06.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 and 23-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16,23-25 and 27-32 is/are rejected.

7)☒ Claim(s) 26 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

(1). Applicants' Remarks and Amendments filed on February 13, 2006 has been received and acknowledged.

Claims 27-32 are newly added.

The rejections of claims 1-16 and 23-26 in the prior Office Action dated November 14, 2005 is removed according to the applicants' Remarks filed on February 13, 2006.

A new ground of rejections for claims 1-16 and 23-32 is introduced as following.

Claim Objections

(2). Claims 5 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The recitation of claims 5 and 6 are identical to the recitation of claims 3 and 4. It fails to claim the inventive subject matters other than that of claims 3 and 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(3). **Claims 1 – 9, 23 - 24** and **31** are rejected under 35 U.S.C. 102(b) as being anticipated by Reinecke et al (US004056497).

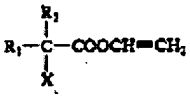
Reinecke et al (US004056497) disclose a acrylic ester copolymers obtained by copolymerizing acrylic esters with α-haloalkanecarboxylic acid vinyl esters and α,β-ethylenically unsaturated carboxylic acids and optionally other unsaturated monomers in aqueous dispersion. The copolymers can be cross-linked with alkalies after the polymerization (Abstract, line 1-5).

The present patentee's invention provides a process for the preparation of aqueous copolymer dispersions capable of being cross-linked in the presence of alkalies by polymerization of a mixture of:

a. 60 to 95 wt%, calculated on the monomer mixture, of at least one acrylic acid ester and/or methacrylic acid ester of a saturated aliphatic alcohol having from 1 to 20 carbon atoms,

b. 0 to 40 wt%, calculated on the monomer mixture, of monomers the homopolymers of which have 2nd order Tg of from –40°C to +150 °C and

c. 0.1 to 10 wt%, calculated on the monomer mixture, of an α-haloalkanecarboxylic acid vinyl esters of the formula (I)

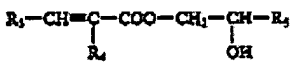


(I)

wherein R_1 and R_2 each represents hydrogen or an alkyl radical having from 1 to 5 carbon atoms and X is fluorine, chlorine, bromine or iodine, in aqueous dispersion in the presence of emulsifiers and/or protective colbids and of free radical initiators, which process comprises using as further reactive monomers

d. 0.1 to 10 wt%, calculated on the monomer mixture of, α,β-ethylenically unsaturated carboxylic acids having from 3 to 8 carbon atoms or their partial ester with saturated aliphatic alcohols having from 1 to 20 carbon atoms and,

e. 0 to 10 wt%, calculated on the monomer mixture, of monomers containing hydroxyl groups and having the formula (II)



(II)

wherein R_3 is hydrogen, a methyl group or the group $-COOR_6$, R_4 and R_5 each is hydrogen or a methyl group and R_6 is hydrogen or an alkyl group having from 1 to 12 carbon atoms.

(Col. 1, line 57 – Col. 2, line 32)

The dispersions of patentee's invention are prepared by free radical polymerization of the monomers in aqueous dispersion using emulsifiers, protective colloids and , optionally regulators (Col. 3, line 12-15). The polymerization temperature is within the range of from 0 °C to + 100 °C, preferably from 20° to 80°C (Col. 3, line 27-29). A foil of polyethylene terephthalate of a 2.5 cm X 20 cm dimension was provided with an adhesive layer 0.3 mm thick (application in wet state). After drying, the foil was joined under slight pressure to a carefully cleaned steel sheet for

measurement of the resistance to peeling (kp/2.5 cm) (Col. 6, line 28-34). The dispersion and the film obtained from the dispersion were extracted with dioxane for determination of the degree of crosslinking (Col. 6, line 51-53).

As to the components of acrylic acid or an ester in the range 40 to 80 wt% , methacrylic acid or an ester in the range 20 to 60 wt% in **claims 1-8** and **23**, Reinecke et al disclose component (a) from 60 to 95 wt% including at least one acrylic acid ester and methacrlic acid ester of a saturated aliphatic alcohol having C_{1-20}. The range of 60 to 95 wt% would include the acrylic acid ester such as ethyl acrylate in the range from 40 to 80 wt% and methacrylic acid ester such as methyl methacrylate in the range from 20 to 60 wt% as claimed.

As to the polymerizable surfactant in **claims 1, 3, 5** and **7**, and formula of surfactant in **claims 2, 4, 6** and **8**, Reinecke et al disclose the component (e) having the formula (II) which is equivalent to formula (I) as claimed, when the setting of patentee's formula (II) are R_3 = H atom, R_4 = H atom or methyl group, R_5 = H, and setting of applicant's formula (I) are R_2 = H atom, m = 1. Since the disclosure of the monomer by Reinecke et al is identical to the formula (I) as claimed. It is reasonable to presume that the component (e) of Reinecke et al would fulfill the utitlity to be a polymerizable surfactant as presently claimed in light of their chemical similarity. The burden is shifted to applicants to establish that the polymerizable surfactant of the present claims is not the same as or obvious as that set forth by Reinecke et al.

As to limitation of **dependent claim 9**, because the aqueous dispersion disclosed by Reinecke et al is substantially identical to the aqueous dispersion in the applicants' claim 3 to 8, it will also be useful in coating pharmaceutical formulations as a film, the drying of film prepared by removing water from aqueous dispersion is anticipated within one ordinary skill in the art, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey,* 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto,* 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(4). **Claims 10 - 14** and **25** are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497) and Barry et al (US005055306).

As to the pharmaceutical formulation in **dependent claim 10**, Barry et al (US005055306) **teach** a sustained-release formulation comprising a core comprising one or more pharmacologically active substances and preferably one or more excipients; and a coating covering substantially the whole surface of the core comprising 100 parts of a water insoluble but water swellable acrylic polymer and from 20 to 70 parts of a water soluble hydroxylated cellulose derivative (Abstract, line 9-17). The acrylic polymer component of the coating is preferably neutral and may comprise a homopolymer or a copolymer, for instance of acrylic acid esters or methacrylic acid esters. Preferably, the acrylic polymer is provided as an aqueous dispersion (Col. 6, line 60-64).

Barry et al **do not teach** the acrylic ester polymer used in pharmaceutical formulation as coating film is acrylic ester copolymer of Reinecke et al.

The advantage of using the acrylic ester copolymer taught by Reinecke et al is a pressure-sensitive adhesive of high heat stability (Abstract, lines 6-7).

Therefore, it would have been obvious at time the invention was made to use the acrylic ester copolymer of Reinecke et al for the coating film of pharmaceutical formulation of Barry et al in order to obtain the above-mentioned advantage. Moreover, the acrylic ester polymer taught by Barry et al is a genus, the acrylic ester copolymer taught by Reinecke et al is species, one

ordinary skill in the art would expect all species work well for the genus, motivated by a reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

As to limitation of **claims 11** and **25**, Barry et al **teach** a granular sustained-release formulation of a pharmacologically active substance presented in the form of a tablet, tablet comprising sufficient granules to provide a predetermined dose or number of dose of pharmacologically active substance and effervescent or water-dispersible ingredients (Abstract, line 1-6). The coating is prepared by forming a solution of, for example, a water soluble hydroxylated cellulose derivative and mixing it with a dispersion of a water swellable acrylic polymer. The aqueous mixture is then used to coat the dried granules, and the coated granules are subsequently dried. (Col. 8, line 38-45). It will be appreciated that the term "granules" as used is intended to also cover other similar particles that might, in conventional sustained-release formulations, normally be referred to as beads or pellets, etc (Col. 8, line 64-68).

Barry et al **do not teach** the acrylic ester polymer to coat the beads of pharmacologically active ingredient is acrylic ester copolymer of Reinecke et al.

The advantage of using the acrylic ester copolymer taught by Reinecke et al is a pressure-sensitive adhesive of high heat stability (Abstract, lines 6-7).

Therefore, it would have been obvious at time the invention was made to use the acrylic ester copolymer of Reinecke et al for the coating of beads in the Barry's et al pharmaceutical formulation in order to obtain the above-mentioned advantage. Moreover, the acrylic ester polymer taught by Barry et al is a genus, the acrylic ester copolymer taught by Reinecke et al is species, one ordinary skill in the art would expect all species work well for the genus, motivated by a reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

As to limitation of **claim 12**, Barry et al disclose the sustained-release formulation (Title).

As to limitation of **claims 13** and **14**, Barry et al disclose, for instance, the pharmacologically active substances that can be used in the sustained-release formulations includes: drug acting on the gastrointestinal system (such as cimetidine), the cardiovascular

system (such as anti-arrythmics e.g. verapamil; beta-adrenoceptor blockers e.g. propranolol, atenolol; anti-hypertensives e.g. methyldopa, levodopa and prazosin) (Col. 7, line 6-13).

(5). **Claims 15** and **16** is rejected under 35 U.S.C. 103(a) as being unpatentable over combined teaching of Reinecke et al (US004056497) and Barry et al (US005055306), in view of Chen (US005939578A), further evidenced by Jonsson et al (US004957745).

As to the limitation of **claims 15** and **16**, Barry et al **do not teach** the beta-blocking adrenergic agent to be metoprolol salts such as tartate, succinate, fumarate or benzoate salt.

However, Chen **teach** a comparative results in beta-adrenoceptor blocking activity to show the patentee's vasomolol with other beta-adrenoceptor blockers such as metoprolol and stenolol and propranolol (Col. 5, line 18-21).

Therefore, it would have been obvious at time the invention was made to include the metoprolol of Chen in the beta-adrenoceptor blockers of Barry et al in view of their functional equivalent beta-adrenergic blockers, motivated by reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

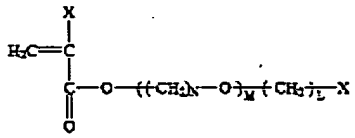
As to the pharmaceutical acceptable metoprolol salts in **claim 16**, it is well known in the art that metoprolol salts including tartrate, succinate, fumarate or benzoate as evidenced by Jonsson et al (US004957745 – Col. 3, line 17-22).

(6). **Claims 27-30** and **32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinecke et al (US004056497) in view of Contrada et al (US006646046B2) and Zellstoffwerke (GB001141165).

As to the limitation of dependent **claims 27-30** and **32**, Reinecke et al **do not teach** the repeating units in his formula (II) (Col. 2, line 24-28) and an alkoxy group with C_{1-20} for terminal group.

However, Contrada et al teach a monomer M1 compound used in aqueous pressure-sensitive adhesive composition with the following formula:

(M1)



where X: hydrogen or an alkyl group, N: 1 – 4, M: 1 – 20, L: 0 – 5 (Col. 3, line 38-54) such as lauroxy polyethyleneglycol monoacrylate, methoxy ethyl acrylate and methoxy polyethyleneglycol methacrylate (Col. 5, line 2-5). Zellstoffwerke (GB001141165) also **teaches** an acrylic films comprising component of an ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group (page 1,line 62-64).

The advantage of using monomer M_1 of Contrada et al is to provide a water-soluble pressure-sensitive adhesive composition having balanced adhesive properties (Col. 2, line 56-59). Furthermore, M_1 monomer of Contrada et al would include the component (e) of Reinecke et al by the setting of N = 2, M = 1, L = 0 and X = H atom in the M_1 monomer formula (Col.3, line 38-54).

The ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group taught by Zellstoffwerke (GB001141165) also include the component (e) of Reinecke et al (US004056497) when number of repeating units is 1.

Therefore, it would have been obvious at time the invention was made to use the M1 monomer compound of Contrada et al for the component (e) of Reinecke et al in order to obtain the above-mentioned advantage. Moreover, in view of their functional equivalent component for acrylic ester copolymer disclosed by Reinecke et al, Contrada et al and Zellstoffwerke, it also would be obvious to use the M1 monomer of Contrada et al and ester of a polyethoxylated product containing at least one acrylic or methacrylic acid ester group taught by Zellstoffwerke (GB001141165) to take place of component (e) of aqueous dispersion of Reinecke et al based on their interchangeability for acrylic ester copolymer, motivated by reasonable expectation of success. *In re O'Farrell,* 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

Allowable Subject Matter

Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-16 and 23-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner: Ives Wu
Art Unit: 1713
Date: April 6, 2006

DAVID W. WU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700